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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,708	06/12/2001	Se-Jin Lee	JHU1320-4	7387

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,708	LEE ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 2-14 are pending. Claims 9, 10, 13, 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 2-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-14 are indefinite because they recite the terms "growth differentiation factor-5 (GDF-5)," "GDF-5 specific antibody," "the GDF-5 polypeptide." Applicant argues that the claims have been amended so that the subject matter is more clearly defined. Applicant's arguments have been fully considered but they are not persuasive. Although the claims, as amended, make it clear that the antibody binds a GDF-5 having an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13, the claims also recite the terms "growth differentiation factor-5 (GDF-

5)," "GDF-5 specific antibody," "the GDF-5 polypeptide" and the GDF-5 in these terms is not limited to "having an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13." The specification intends the term "GDF-5" to encompass polypeptides produced by minor modifications of GDF-5, and which have substantially equivalent activity to GDF-5. Such modifications may be deliberate or spontaneous (page 10, lines 1-10). Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "GDF5" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. Hence, the metes and bounds of GDF-5 in the terms "growth differentiation factor-5 (GDF-5)," "GDF-5 specific antibody," "the GDF-5 polypeptide" are not clearly set forth.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 2-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-14 are indefinite because they recite the terms "GDF-5 specific antibody" and "specifically binds" (claim 2). Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "specific" and "specifically binds" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of these terms. The metes and bounds are not clearly set forth.

Claims 2-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-14 are indefinite over the recitation of "altered expression" and "comparable specimens obtained from normal subjects" (claim 2). The claims indicate that "altered expression" is indicated by a comparison to "comparable specimens obtained from normal subjects." Accordingly, "altered expression" is relative to "comparable specimens obtained from normal subjects." However, the specification provides no guidance that would allow those skilled in the art to determine, with a reasonable degree of confidence, when a specimen is comparable and when it is not comparable. In addition, the term "normal subjects" is a relative term. The term "normal subjects" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. One of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicants argue that "normal" is used in the context of "altered expression;" that the term "normal" has a plain meaning; that the specification discloses "normal" expression patterns; that the skilled artisan would know to compare expression with control specimens; that normal expression would be apparent and readily ascertained by the skilled artisan. Applicant's arguments have been fully considered but they are not persuasive.

When read in light of the specification, the intended scope of the claims become unclear. The specification does not disclose the literal language of the claims. Of course,

the test for definiteness is not literal support but whether one skilled in the art would understand the bounds of the claim when read in light of the specification.

The following passage from the specification seems to be the most relevant for construing the claim:

> For purposes of the invention, an antibody specific for GDF-5 polypeptide may be used to detect the level of GDF-5 in biological fluids and tissues. Any specimen containing a detectable amount of antigen can be used. A preferred sample of this invention is tissue of uterine origin, specifically endometrial tissue or skeletal tissue such as bone and cartilage. The level of GDF-5 in the suspect cell can be compared with the level in a normal cell to determine whether the subject has a GDF-5-associated cell proliferative disorder. Page 15, full paragraph 1.

These various embodiments disclosed in the specification do not correspond in scope to the metes and bounds of the claims. On one hand, the specification describes comparing the level of GDF-5 in a "suspect cell." On the other hand, the claims describe detecting altered expression of GDF-5 in a subject in need thereof, the subject suspected of having altered expression of the GDF-5. The specification provides no guidance that would allow those skilled in the art to determine, with a reasonable degree of confidence, when a cell is suspect and when it is not suspect. The specification provides no guidance that would allow those skilled in the art to determine, with a reasonable degree of confidence, how to construe a "suspect cell" as a subject in need thereof, the subject suspected of having altered expression of the GDF-5. Thus, the metes and bounds of the claimed invention are unclear.

Claims 2-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting GDF-5 having an amino

acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13 in uterine, endometrial, or skeletal tissue, does not reasonably provide enablement for detecting altered expression of GDF-5 in a person in need thereof or in the subject suspected of having altered expression of the GDF-5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to or encompass detecting altered expression of GDF-5 in a subject in need thereof, the subject suspected of having altered expression of the GDF-5. The GDF-5 expression in specimens from such subjects is compared to GDF-5 expression in comparable specimens from normal subjects. The specification lacks guidance for, and working examples of, subjects in need of detecting altered expression of GDF-5, the subject suspected of having altered expression of the GDF-5. Given this lack of guidance and working examples, the skilled artisan is left to an undue amount of extensive experimentation involving extensive testing of any and/or all subjects and is left to determine if any and/or all of such subjects are in need of detecting altered expression of GDF-5, the subject suspected of having altered expression of the GDF-5. To practice the claimed invention in a manner consistent with the breadth of the claims would not require just a repetition of work that is described in the present application but a substantial inventive contribution on the part of a skilled practitioner which would involve the determination of those subjects in need of detecting altered expression of GDF-5, the subject suspected of having altered expression of the GDF-5. It is this additional characterization, which is not provided for in the present specification, of that single disclosed, naturally occurring GDF5 protein and the disorders or abnormalities

with which it is associated that is required in order to obtain the information needed to permit one to practice the claimed invention that constitutes undue experimentation. The skilled is left to an undue amount of unduly extensive, random, trial and error experimentation in order to practice the claimed invention in a manner commensurate in scope with the claims. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

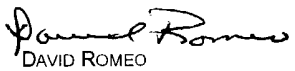
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FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
APRIL 16, 2004